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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 2005D-0330, Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods

Dear Docket Officer:

The Food and Drug Administration published in the Federal Register a Draft Guidance for Industry and FDA Review Staff on Collection of Platelets by Automated Methods on October 3, 2005. Virginia Blood Services (VBS) would like to take this opportunity to offer some comments regarding this document.

Virginia Blood Services is a non-profit community based blood donor center headquartered in Richmond, Virginia serving central Virginia since 1974. VBS is a member of America's Blood Centers as a FDA licensed facility and is an AABB accredited donor center. Virginia Blood Services is the sole blood provider for 21 hospitals in the region including two major university-based medical centers with trauma centers and expanding solid organ and hematopoietic stem cell transplant programs. The collection goal for VBS in 2006 is 90,000 whole blood units and 10,500 single donor platelets sought by donations at fixed collection centers, and mobile drives.

This Draft Guidance represents an extensive revision of previous guidance. Our organization has grave concerns that the implementation of this draft guidance as proposed will have unintended negative consequences on the availability of platelet pheresis products. Ultimately, the care of all the patients we serve will be threatened by the exacerbation of platelet shortages. The anticipated benefits of medical and technical advancements to reduce morbidity and mortality for many of the most desperate patients such as oncology and hematopoietic stem cell transplant patients might fall short of the promise due to limited availability of life saving components in an era when it is technologically feasible. While the intent of regulatory guidelines is to safeguard both the donor and recipient, there does not appear to be a collective experience of greater risk or adverse events for the donor as a foundation for this draft guidance. However, the risk for a detrimental impact on the patient recipients by limiting platelet collections could be far more serious than considered in the initial risk/benefit analysis of this plan. Our plea with this letter is to request promotion of further discussion by the public and panels of experts to discuss the merits and consequences of implementing this draft guidance.

While the guidance document addresses multiple aspects of plateletpheresis, we would like to highlight our concerns by discussing some selected topics.

- It is ironic that this guidance has been proposed following the tremendous nationwide efforts by blood centers to redirect and convert many whole blood donors to become dedicated pheresis donors. The proposed restriction of the number of products collected from individual donors to no more than 24 products per year (including double and triple components/procedure) instead of the current limitation of 24 procedures per year will reverse the progress made to enhance the platelet supply. It will severely limit the number of products collected per year with an estimated loss of 25-30% of platelet pheresis components for our center while the anticipated increase in stem cell transplants and needs are expected to double. Additionally, the proposed guidance further restricts the volume of plasma collected.

- The proposed draft guidance outlines requirements for physicians to be available within 15 minutes for emergency medical situations. In effect, platelet pheresis collections will only be feasible at a single site for our organization and thus threatens to eliminate an additional 50-75% of platelet pheresis collections. The potential of auxiliary collection sites, mobile drives and expanded hours will be eliminated. Dedicated plateletpheresis donors will be required to donate at a single site that may not be convenient and at times that are not optimal. It may then come as no surprise if donations dwindle because organizations are not able to accommodate the needs of these donors. Unlike therapeutic apheresis procedures that are used to treat fragile, complicated patients for sometimes life threatening conditions, the automated donor collections involve healthy donors and are considered safe with very few donor reactions. Physicians at blood collection facilities (pathologists and hematologists) typically do not have the background and intensive training of experienced emergency response teams. The reliance upon a sole physician as a single emergency responder without the support of emergency trained teams, access to specialized equipment and pharmaceutical interventions does not realistically provide the envisioned safety margin even within a 15 minute timeframe. The rapid response of trained emergency teams with capabilities for urgent transport and auxiliary resources offer a more realistic and reliable plan to handle emergency situations for our donors and staff.

- Pheresis platelet availability will be further reduced by the requirement to perform both pre and post donation platelet and WBC counts. This type of data is not currently available at some auxiliary sites and mobile drives. The current minimum standard of 150,000 for a pre-donation platelet count does not appear to cause adverse conditions over the course of multiple donations.

It is our hope that this letter expressing our concerns will help to prompt further review of the proposed requirements in the draft guidance. While we support advocacy for donor safety, we argue that the perceived gains by these proposed measures might be eclipsed by the unforeseen toll on platelet availability and negatively impact the health of the very patients we aim to serve Thank you for the opportunity to comment on this docket.

Respectfully,

Janice K. Jesse MD

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